TAB B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Greg Swords)) Art Unit: 3774
Serial No. 10/517,843) ·
Filed: July 12, 2005	Examiner: Suba Ganesan
For: Craniofacial Implant) Attorney Docket No.: 37370/339252

DECLARATION OF DON O. KIKKAWA UD

- My name is Don KIKKAUCI am over the age of 21, and I am competent 1. to make this declaration based upon my personal knowledge.
- I am a surgeon who uses the TITANTM implant, which I understand is the product 2. made according to the above-referenced application.
- The TITANTM implant is a porous polyethylene matrix having a metal mesh 3. embedded therein. In some versions of the implant, there is a barrier coating on one or both sides. The TITANTM implant provides clear and distinct benefits over other craniofacial implants previously on the market.
- First, porous polyethylene implants for orbital reconstruction without a surgical grade 4. metal mesh do not always meet my needs because they do not provide adequate strength needed for certain surgeries, they are not always malleable, they have less shape memory than metal mesh alone, and they are not readily visualized on postoperative radiographs or CT scans. Second, metal mesh alone (not contained within a sheet of thermoplastic resin)

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does not always meet my needs because it does not allow for cellular ingrowth, it does not provide a smooth solid barrier surface, which is sometimes needed to completely prevent passage of fluids and other biological matter, and it can be difficult to insert through small incisions because of its sharp or irregular edges.

- When the TITANTM implant was introduced, it was the first product on the market to 5. combine porous polyethylene and titanium mesh into one implant by embedding the mesh within polyethylene, obtaining the benefits of both materials.
- Upon its introduction, I was (and I continue to be) quite pleased with the features that the TITANTM implant provides. It combines strength and flexibility, so that I can bend the implant and it maintains its shape. It also provides different options - implants that allow fibrovascular ingrowth on both sides (porous/porous), fibrovascular ingrowth on only one side (porous/barrier), or preventing ingrowth completely (barrier/barrier). I currently use the TITAN™ implant in most of my large or complex orbital reconstruction surgeries.
- My decision to use (and continue to use) the TITAN™ implant is not influenced by 7. cost, advertising, my relationship with Porex, nor any other economic or commercial factors. I choose to use TITANTM implants because the features they provide are highly superior to any other product on the market. The combination of porous polyethylene with a surgical grade metal mesh embedded therein is why I (and many of my colleagues) continue to purchase and use the TITANTM implant.
- As the person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code.

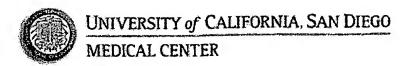
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Don Kikkawa, M.D.

Ophthalmology (Oculoplastic Surgery)

REQUEST AN APPOINTMENT WITH THIS DOCTOR.

Dr. Kikkawa serves as Division Chief of Ophthalmic Plastic and Reconstructive Surgery. This specialty combines traditional studies and patient care as an ophthalmologist with a fellowship in reconstruction and plastic surgery around the eyes. The extensive training uniquely qualifies these specialists to perform delicate surgery on the eyelids, around the eyes, the drainage system, and on the bones around of the eye. Dr. Kikkawa finds the field very gratifying; reversing the effects of aging, restoring a normal appearance to disfigured trauma or diseased patients, and eliminating vision-threatening tumors.

Respected for his knowledge and surgical experience, patients travel to San Diego from throughout the United States, as well as other countries, for Dr. Kikkawa's skills. He has hosted several highly praised medical conferences for his colleagues and selected by them to Best Doctors in America. Additionally, Dr. Kikkawa serves as one of three Shiley specialists that comprise our unique Thyroid Eye Clinic to treat patients with this disfiguring and vision threatening disease.

Board Certification:

Ophthalmology

Experience:

Dr. Kikkawa is Chief of Ophthalmic Plastic and Reconstructive Surgery at UCSD Healthcare's Shiley

Eye Center.

Education:

St. Louis University School of Medicine

St. Louis, Missouri Doctor of Medicine

Training:

Residency in Ophthalmology Jules Stein Eye Institute University of California

Los Angeles, California

Hospital Affiliations:

UCSD Thornton Hospital, La Jolla UCSD Medical Center, Hillcrest

Office Address:

Shiley Eye Center

9415 Campus Point Drive La Jolla, CA 92037 View Map | Driving Directions

- Shiley Eye Center at UCSD Medical Center
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